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FAULKNER, D

ART UNIT	PAPER NUMBER
1617	7

DATE MAILED: 04/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/082,109

Applicant
Haworth et al

Examiner
Faulkner, D.

Group Art Unit
1617



☒ Responsive to communication(s) filed on Oct 25, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-21 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-16 and 18-21 is/are rejected.

☒ Claim(s) 17 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

D. Faulkner

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. The examiner acknowledges receipt of the amendment and response received on 10/25/99.
2. Applicant's arguments regarding Kahleyss have been convincing, and kayleyss has been removed from the rejection of record.
3. Claim 17 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

4. Claim 1-16, 20 and 21 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-16 and 18- 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "a method of extraction from rosemary" is not enabled for a method of extraction from all organic components. The extractions listed on pages 3-6 of the specification does not reasonably provide enablement for all organic materials. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

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The specification does not provide sufficient enabling disclosure for the claimed method of extraction as applied to organic materials in general.

For rejection under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Breadth of claims.
- 2) Nature of invention.
- 3) State of prior art.
- 4) Level of ordinary skill in the art.
- 5) Level predictability in the art.
- 6) Amount of direction and guidance provided by the inventor.
- 7) Existence of working examples.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breath of the claimed invention includes one particular species within the scope of the generic disclosure, with organic substitutents such as rosemary. The nature of the invention is in the field of extraction of antioxidants wherein, applicants are claiming the process of extraction utilizing commercially available rosemary products compared with rosemary extracts that are extracted in the laboratory using various solvents for extraction.

The state of the prior art is what prior art knows about the nature of the invention. The state of the prior art is such that various herbal extracts for use as natural antioxidants are being

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explored, including rosemary, and vitamin E and sage. The active component of rosemary, Carnosic acid is known to be the major contributor of antioxidant activity in rosemary.

The level of ordinary skill in the art is high but, only in the art of extractions of various solvents utilizing rosemary. The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by applicants. In the instant invention the predictability is very low and consequently, the need for higher levels of direction and guidance by applicants. However, the amount of direction and guidance provided by applicants is very limited to four experiments, (labeled methods on pages 8-15). All methods utilize solvent extraction of rosemary. There is no evidence in the specification that established correlation between the experiments and the claimed utilities. See Ex parte Mass, 9 USPQ2d 1746, 1987. The quantity of experimentation required to use the organic components claimed in the instant invention, based on applicants limited disclosure would be undue burden because, one of ordinary skill in the art would have to perform a significant amount experiments. It is suggested that the claims be limited to a method of extracting materials from rosemary, (note summary of invention at pages 3-6).

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being

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indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially similar" in claims 11 and 13 is a relative term which renders the claim indefinite. The term "substantially similar" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The applicant can overcome this rejection by deleting this word.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

8. Claims 1 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Reeves. Reeves teaches the process of purification of organic material, psyllium husk, using fluorinated hydrocarbons such as tetrafluoroethane, col. 3 lines 53 et seq. see the terms fluorinated hydrocarbons in liquid form which are considered as organic solvents. The representative psyllium husk is inclusive of the broad "organic material" of the claims and is also inclusive of the term botanical material. The impurities of the psyllium husk equal the liquid oily material that is withdrawn from the psyllium seed husk. See col. 3 lines 64 through col. 4 (see especially no. 1-3 at col. 4).

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Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 3, 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves, US patent 5,085,785.

Reeves teaches the process of purification of organic material, psyllium husk, using fluorinated hydrocarbons such as tetrafluoroethane, see claim 13.

It is noted that fluorinated hydrocarbons in liquid form are considered as organic solvents. The representative psyllium husk is inclusive of the broad "organic material" of the claims and is also inclusive of the term botanical material. The liquid material that is withdrawn is noted on col. 3 lines 64 through col. 4 (see especially no. 1-3 at col. 4).

The additional solvent blend is described in the extraction/purification process of the organic material at col. 3 lines 5-8 which describes additional solvent mixtures of carbon tetrachloride and dichloroethane.

Reeves is silent as to the amount of tetrafluorethane used in the solvent extraction process.

It would have been obvious to one of ordinary skill in the art to utilize an effective amount the particular blends of tetrafluorethane for use as a solvent in the extraction/purification process of an organic material. The motivation for this variation is that variation of a particular amount of

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solvent is considered as a result effective parameter well within the skill of the artisan. In the Reeves patent, the same result is achieved-- the extraction of an organic solvent

Response to Arguments

11. Applicant's arguments filed 10/25/99 have been fully considered but they are not persuasive.

The applicant argues that the references do not teach or suggest to one skilled in the art a high-yielding antioxidant extraction method accomplished with minimal oxidative destruction of the subject compound through the use of TFE compounds.

It is noted that applicants claims especially generic claim one does not require extraction of an antioxidant but is a process for extracting any organic component from organic material. Reeves meets this limitation. Applicant argues that Reeves teaches density mediated purification of seed husks by manipulating pressure and temperature under which the fluorinated hydrocarbons are combined with the impure husks. However, as noted in the examiners rejection Reeves teaches the process of purification of organic material using fluorinated hydrocarbons such as TFE, see claim 13.

It is further noted that the applicants process uses the language "comprising the steps of", so in the event that Reeves has incorporated additional process steps in their inventions, applicant does not preclude the use of additional process steps using comprising language.

Applicant states that neither cited reference disclose all of the features of the claimed invention, either singularly or in combination, and that it would not be obvious to one skilled in the art to modify one reference in view of the other to arrive at the same conclusion as that claimed in the

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subject invention.

The examiner respectfully responds that the Reeves reference clearly establishes the fact that two organic solvents may be used in purification processes, (a process which is used to increase the yield of the organic substituent, and decrease the yield of unwanted byproducts). See Reeves at col. 2 lines 55-62 where he teaches tetraflouroethane, triflouoroethane, chloropentaflouroethane.... and mixtures thereof.

Regarding applicants data in the specification on pages 7-16, , it is applicants burden to demonstrate that results are unexpected and significant. Applicant has the burden of emplaning proffered data, see MPEP. section 716.01 (c).

In this case it is not seen how the data demonstrates unexpected results in order to overcome the established prima facie case.

Furthermore, unexpected results are to be commensurate in scope with the claimed invention, demonstrating criticality of a claimed range. (see MPEP. section 716.02 (c).

Since applicants specification examples demonstrate data for only the particular solvent blends demonstrated, the claims are not commensurate in scope with the evidence of record.


Applicant's arguments regarding Kahleyss have been convincing, and kayleyss has been removed from the rejection of record.

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1a. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Faulkner whose telephone number is (703) 305-4043. The examiner can normally be reached on Monday-Friday from 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Right can be reached on (703) 305-4043. The fax phone number for the organization where this application or proceeding is assigned is (703) 703-305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


JOHN RIGHT
SUPERVISOR EXAMINER
GROUP 1600

D. Faulkner

D.S.F.

April 3, 2000